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NATIONAL  
**GUIDELINE**  
CLEARINGHOUSE

## General

### Guideline Title

Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. Report of the Guideline Development Subcommittee of the American Academy of Neurology.

### Bibliographic Source(s)

Morris GL 3rd, Gloss D, Buchhalter J, Mack KJ, Nickels K, Harden C. Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2013 Oct 15;81(16):1453-9. [40 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

## Recommendations

### Major Recommendations

Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (Class I-IV) are provided at the end of the "Major Recommendations" field.

In Children with Epilepsy, Is Using Adjunctive Vagus Nerve Stimulation (VNS) Therapy for Seizure Frequency Reduction Better Than Not Using Adjunctive VNS therapy for Seizure Frequency Reduction?

#### Conclusion

Based on data from 14 Class III studies, VNS is possibly effective in achieving >50% seizure frequency reduction (responder rate). In the pooled analysis of 481 children, the responder rate was 55% (95% confidence interval [CI] 51%–59%), but there was significant heterogeneity in the data. Two of the 16 studies were not included in the analysis because either they did not provide information about responder rate or they included a significant number (>20%) of adults in their population. The pooled seizure freedom rate was 7% (95% CI 5%–10%).

#### Recommendation

VNS may be considered as adjunctive treatment for children with partial or generalized epilepsy (Level C).

#### Clinical Context

VNS may be considered a possibly effective option after a child with medication-resistant epilepsy has been declared a poor surgical candidate or has had unsuccessful surgery.

## In Patients with Lennox-Gastaut Syndrome (LGS), Is Using Adjunctive VNS Therapy for Seizure Frequency Reduction Better Than Not Using Adjunctive VNS Therapy for Seizure Frequency Reduction?

### Conclusion

Based on data from 4 Class III studies, VNS is possibly effective in achieving >50% seizure frequency reduction in patients with LGS. The pooled analysis of 113 patients with LGS (including data from articles with multiple seizure types where LGS data were parsed out) yielded a 55% (95% CI 46%–64%) responder rate.

### Recommendation

VNS may be considered in patients with LGS (Level C).

### Clinical Context

The responder rate for patients with LGS does not appear to differ from that of the general population of patients with medication-resistant epilepsy.

## In Patients with Epilepsy, Is Using VNS Associated with Mood Improvement?

### Conclusion

Based on data from 2 Class III studies, VNS is possibly effective for mood improvement in adults with epilepsy.

### Recommendation

In adult patients receiving VNS for epilepsy, improvement in mood may be an additional benefit (Level C).

### Clinical Context

Depression is a common comorbidity for people with epilepsy. VNS may provide an additional benefit by improving mood in some patients; however, the potential for mood improvement should be considered a secondary rather than a primary reason for VNS implantation. The evidence does not clearly support an independent effect on mood in this complex population.

## In Patients with Epilepsy, Is VNS Use Associated with Reduced Seizure Frequency Over Time?

### Conclusion

Based on data from 2 Class III studies, VNS is possibly associated with an increase in  $\geq 50\%$  seizure frequency reduction rates of 7% from 1 to 5 years postimplantation.

### Recommendation

VNS may be considered progressively effective in patients over multiple years of exposure (Level C).

### Clinical Context

The loss of medication efficacy over time is a challenging aspect of epilepsy management. The evidence of maintained efficacy in the long term and the trend toward improvement over time make VNS an option.

## In Patients Undergoing VNS Therapy, Does Rapid Stimulation (Usual VNS Settings Are 7 Seconds "On" and 30 Seconds "Off") Improve Seizure Frequency More Often Than Standard Stimulation Settings (30 Seconds "On" and 300 Seconds "Off")?

### Conclusion

These 3 Class III studies were underpowered to detect a difference in efficacy between rapid stimulation (7 seconds "on," 30 seconds "off") used either after standard stimulation (30 seconds "on," 300 seconds "off") was unsuccessful or as an initial treatment setting.

### Recommendation

Optimal VNS settings are still unknown, and the evidence is insufficient to support a recommendation for the use of standard stimulation vs. rapid stimulation to reduce seizure occurrence (Level U).

### Clinical Context

Rapid cycling increases the duty cycle and hastens the need for battery replacement; therefore, when used, the efficacy of rapid cycling should be carefully assessed.

#### In Patients Undergoing VNS Therapy, Does Using Additional Magnet-Activated Stimulation Trains for Auras or at Seizure Onset Interrupt Seizures Relative to Not Using Additional Magnet-Induced Stimulation Trains for Auras or at Seizure Onset?

##### Conclusion

Based on data from 2 Class III studies, seizure abortion with magnet-activated stimulation is possibly associated with overall response to VNS therapy. Based on 3 Class III studies, magnet-activated stimulation may be expected to abort seizures one-fourth to two-thirds of the time when used during seizure auras (one Class III study omitted because it was not generalizable).

##### Recommendation

Patients may be counseled that VNS magnet activation may be associated with seizure abortion when used at the time of seizure auras (Level C) and that seizure abortion with magnet use may be associated with overall response to VNS treatment (Level C).

#### In Patients Undergoing VNS Therapy, Have New Safety Concerns Emerged Since the Last Assessment?

##### Clinical Context

Current physician attention to intraoperative rhythm disturbances from VNS use need not be changed. The paroxysmal nature of epilepsy poses a challenge for identifying a cardiac rhythm disturbance as device-related rather than as an additional seizure manifestation. Video electroencephalogram (EEG) and electrocardiogram (ECG) monitoring of new-onset events that might be cardiac-related would be warranted to exclude this possibility in what is likely to be a small number of patients. Reduced sudden unexpected death in epilepsy (SUDEP) rates over time is an important finding associated with VNS therapy; in a cohort of 1,819 individuals followed 3,176.3 person-years from VNS implantation, the SUDEP rate was 5.5 per 1,000 over the first 2 years but only 1.7 per 1,000 thereafter. The clinical importance of the effect of VNS on sleep apnea and treatment is unclear, but caution regarding VNS use in this setting is suggested.

#### In Children Undergoing VNS Therapy, Do Adverse Events (AEs) Differ from Those in Adults?

##### Clinical Context

Children may have greater risk for wound infection than adults due to behaviors more common in children. Extra vigilance in monitoring for occurrence of site infection in children should be undertaken.

##### Definitions:

##### Classification of Evidence for Therapeutic Intervention

Class I: A randomized, controlled clinical trial of the intervention of interest with masked or objective outcome assessment, in a representative population. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

The following are also required:

- a. Concealed allocation
- b. Primary outcome(s) clearly defined
- c. Exclusion/inclusion criteria clearly defined
- d. Adequate accounting for dropouts (with at least 80% of enrolled subjects completing the study) and crossovers with numbers sufficiently low to have minimal potential for bias.
- e. For noninferiority or equivalence trials claiming to prove efficacy for one or both drugs, the following are also required\*
  1. The authors explicitly state the clinically meaningful difference to be excluded by defining the threshold for equivalence or noninferiority.
  2. The standard treatment used in the study is substantially similar to that used in previous studies establishing efficacy of the standard treatment (e.g., for a drug, the mode of administration, dose and dosage adjustments are similar to those previously shown to be effective).
  3. The inclusion and exclusion criteria for patient selection and the outcomes of patients on the standard treatment are comparable to those of previous studies establishing efficacy of the standard treatment.
  4. The interpretation of the results of the study is based upon a per protocol analysis that takes into account dropouts or crossovers.

Class II: A randomized controlled clinical trial of the intervention of interest in a representative population with masked or objective outcome assessment that lacks one criteria a–e above or a prospective matched cohort study with masked or objective outcome assessment in a representative population that meets b–e above. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.\*\*

Class IV: Studies not meeting Class I, II, or III criteria including consensus or expert opinion.

\*Note that numbers 1-3 in Class Ie are required for Class II in equivalence trials. If any one of the three is missing, the class is automatically downgraded to Class III.

\*\*Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

#### Classification of Recommendations

Level A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.\*)

Level B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

Level C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

Level U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

\*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Epilepsy

### Guideline Category

Assessment of Therapeutic Effectiveness

Management

Treatment

### Clinical Specialty

Neurological Surgery

Neurology

## Intended Users

Physicians

## Guideline Objective(s)

To evaluate the current evidence regarding efficacy and safety of vagus nerve stimulation (VNS) for epilepsy, currently approved as adjunctive therapy for partial-onset seizures in patients >12 years

## Target Population

Adults and children >12 years with epilepsy

## Interventions and Practices Considered

Vagus nerve stimulation (VNS)

## Major Outcomes Considered

- Degree of mood improvement
- Degree of seizure reduction
- Incidence of explantation
- Incidence and severity of complications

## Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

The guideline developers searched MEDLINE, EMBASE, and Web of Science (1996–February 2012) using the key words "seizures," "epilepsy," "mood disorder," "depressive disorder," "vagus nerve stimulation," and "neurostimulation" (see Appendices e-3–e-5 of the data supplement [see the "Availability of Companion Documents" field]). The search yielded 1,274 abstracts, all of which were reviewed for relevance by at least 2 panel members; 1,058 abstracts were not relevant to provide answers to the questions. Two members of the guideline development committee independently reviewed the full text of 216 articles.

### Number of Source Documents

216

### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

## Classification of Evidence for Therapeutic Intervention

Class I: A randomized, controlled clinical trial of the intervention of interest with masked or objective outcome assessment, in a representative population. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

The following are also required:

- a. Concealed allocation
- b. Primary outcome(s) clearly defined
- c. Exclusion/inclusion criteria clearly defined
- d. Adequate accounting for dropouts (with at least 80% of enrolled subjects completing the study) and crossovers with numbers sufficiently low to have minimal potential for bias.
- e. For noninferiority or equivalence trials claiming to prove efficacy for one or both drugs, the following are also required\*
  1. The authors explicitly state the clinically meaningful difference to be excluded by defining the threshold for equivalence or noninferiority.
  2. The standard treatment used in the study is substantially similar to that used in previous studies establishing efficacy of the standard treatment (e.g., for a drug, the mode of administration, dose and dosage adjustments are similar to those previously shown to be effective).
  3. The inclusion and exclusion criteria for patient selection and the outcomes of patients on the standard treatment are comparable to those of previous studies establishing efficacy of the standard treatment.
  4. The interpretation of the results of the study is based upon a per protocol analysis that takes into account dropouts or crossovers.

Class II: A randomized controlled clinical trial of the intervention of interest in a representative population with masked or objective outcome assessment that lacks one criteria a–e above or a prospective matched cohort study with masked or objective outcome assessment in a representative population that meets b–e above. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.\*\*

Class IV: Studies not meeting Class I, II, or III criteria including consensus or expert opinion.

\*Note that numbers 1-3 in Class Ie are required for Class II in equivalence trials. If any one of the three is missing, the class is automatically downgraded to Class III.

\*\*Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

## Methods Used to Analyze the Evidence

### Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Two members of the guideline development committee independently reviewed the full text of 216 articles. Articles using the patient as his or her own control were included only if the patient's assessment of seizures (e.g., seizure diary) was independent of the assessing physician's. Therefore, in this update, those articles that used a patient- or parent-maintained seizure diary as an assessment of seizure frequency were deemed as meeting criteria for Class III evidence (see Appendix e-6 of the data supplement for classification scheme [see the "Availability of Companion Document" field]). Reviews and Class IV reports were excluded, except for case reports of serious safety concerns. Because the guideline developers found only one article at an evidence level higher than Class III, they cited and included in the evidence tables (see Tables e-1 and e-2 of the data supplement) Class III articles when more than one of those articles supported a conclusion in response to a question. Some studies included several seizure types and spanned age groups; these were cited in answer to the question appropriate for the majority of the study patients if the specific subset could not be parsed out. All Class III epilepsy and Lennox-Gastaut syndrome (LGS) efficacy studies in children were reviewed for adverse effects (AEs), as were Class IV studies that had >50 patients. However, serious AEs are reported in the original guideline document even if they came from single cases or case series. Retrieved articles did not systematically assess AEs but were descriptive.

# Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Recommendations are based on the strength of the evidence (see the "Rating Scheme for the Strength of the Recommendations" field).

## Rating Scheme for the Strength of the Recommendations

### Classification of Recommendations

Level A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)\*

Level B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

Level C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

Level U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

\*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Drafts of the guideline have been reviewed by at least 3 American Academy of Neurology (AAN) committees, a network of neurologists, Neurology® peer reviewers, and representatives from related fields.

The original guideline document was approved by the Guideline Development Subcommittee on January 12, 2013; by the Practice Committee on February 7, 2013; and by the AAN Board of Directors on June 11, 2013.

This guideline was endorsed by the American Epilepsy Society on January 15, 2013.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Appropriate management of patients with epilepsy

## Potential Harms

- Infection risk at the vagus nerve stimulation (VNS) implantation site in children is increased relative to that in adults.
- Case reports regarding complications related to VNS use are detailed in Table e-3 of the data supplement (see the "Availability of Companion Documents field").

## Qualifying Statements

### Qualifying Statements

This statement is provided as an educational service of the American Academy of Neurology (AAN). It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved. The clinical context section is made available in order to place the evidence-based guideline(s) into perspective with current practice habits and challenges. Formal practice recommendations are not intended to replace clinical judgment.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

## IOM Domain

Effectiveness

# Identifying Information and Availability

## Bibliographic Source(s)

Morris GL 3rd, Gloss D, Buchhalter J, Mack KJ, Nickels K, Harden C. Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2013 Oct 15;81(16):1453-9. [40 references] [PubMed](#)

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2013 Oct 15

## Guideline Developer(s)

American Academy of Neurology - Medical Specialty Society

## Source(s) of Funding

American Academy of Neurology (AAN)

## Guideline Committee

Guideline Development Subcommittee of the American Academy of Neurology (AAN)

## Composition of Group That Authored the Guideline

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## Financial Disclosures/Conflicts of Interest

### Conflict of Interest

The American Academy of Neurology (AAN) is committed to producing independent, critical and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects. Drafts of the guideline have been reviewed by at least 3 AAN committees, a network of neurologists, Neurology® peer reviewers, and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at [www.aan.com](http://www.aan.com)

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### Disclosure

G. Morris serves on the speakers bureaus of Eisai, UCB, Cyberonics, Lundbeck, and Pfizer; estimates 5% of his clinical effort is spent on vagus nerve stimulation (VNS); and receives research support from Aurora Health Care.

D. Gloss reports no disclosures.

J. Buchhalter estimates that 25% of his clinical effort is spent on electroencephalogram (EEG) and video-EEG and epilepsy surgery evaluation; serves as a contributing associate editor for Epilepsy Currents and Clinical Neurology News; and is on the editorial board of Pediatric Neurology.

K. Mack serves as a Section Editor for Neurology®.

K. Nickels reports no disclosures.

C. Harden serves on the scientific advisory board for UCB and UCB Pregnancy Registry; serves as a journal contributing editor for Epilepsy Currents; serves on the speakers bureaus of Pfizer, UCB, and GlaxoSmithKline; and is a consultant for Upsher-Smith.

Go to [Neurology.org](http://Neurology.org)  for full disclosures.

## Guideline Endorser(s)

American Epilepsy Society - Disease Specific Society

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the [AAN Web site](http://AAN Web site) .

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 201 Chicago Avenue South, Minneapolis, MN 55415.

## Availability of Companion Documents

The following are available:

- Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. Data supplement (e-appendices, e-references, e-table). St. Paul (MN): American Academy of Neurology; 2013. Electronic copies: Available from the [American Academy of Neurology \(AAN\) Web site](http://American Academy of Neurology (AAN) Web site) .
- Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. Slide presentation. St. Paul (MN): American

Academy of Neurology; 2013. Electronic copies: Available from the [AAN Web site](#) .

- Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. AAN summary of evidence-based guideline for clinicians. St. Paul (MN): American Academy of Neurology; 2013. 2 p. Electronic copies: Available from the [AAN Web site](#) .
- Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. Case study. St. Paul (MN): American Academy of Neurology; 2013. 5 p. Electronic copies: Available from the [AAN Web site](#) .
- Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. Podcast. St. Paul (MN): American Academy of Neurology; 2013. Electronic copies Available from the [AAN Web site](#) .
- Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. CME course. St. Paul (MN): American Academy of Neurology; 2013. Available from the [AAN Web site](#) .
- Vagus nerve stimulation in the treatment of epilepsy. Payment policy perspectives; 2013. 7 p. Electronic copies: Available from the [AAN Web site](#) .
- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Electronic copies: Available from the [AAN Web site](#) .

## Patient Resources

The following is available:

- Vagus nerve stimulation for the treatment of epilepsy. Summary of evidence-based guideline for patients and their families. St. Paul (MN): American Academy of Neurology. 2013. 2 p. Electronic copies: Available from the [American Academy of Neurology \(AAN\) Web site](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

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## Copyright Statement

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## Disclaimer

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